IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ISOMERIC PHARMACY SOLUTIONS, LLC, a limited liability company, and WILLIAM O. RICHARDSON, RACHAEL S. CRUZ, and JEFFERY D. BROWN, individuals, Defendants	Case No. 2:17-cv-00852-RJS **CONSENT DECREE OF PERMANENT INJUNCTION** Judge Robert J. Shelby

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Injunction against defendants, Isomeric Pharmacy Solutions, LLC ("Isomeric"), a limited liability company, and William O. Richardson, Rachael S. Cruz, and Jeffery D. Brown, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint for Permanent Injunction ("Complaint") states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction,

into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, an article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling does not bear adequate directions for use.

6. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

8. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval.

9. For the purposes of this Decree, the following definitions shall apply:

A. "Bulk drug substance" shall mean any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances;

B. "CGMP" shall refer to the current good manufacturing practice requirements for drugs within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211. In determining whether Defendants are compounding drugs at an outsourcing facility in compliance with CGMP, Defendants, their expert consultants, and FDA may consider any regulations and/or guidance that FDA has issued with respect to CGMP for outsourcing facilities;

C. "Compound" and "compounding" shall include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug;

D. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repacking, labeling, and holding drugs;

E. "Distribution" and "distributing" shall mean to sell, trade, ship, or deliver and shall include, but not be limited to, delivery or shipment to a healthcare setting for administration and dispensing to a patient or to an agent of a patient;

F. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1);

G. "Drug product" shall mean a finished dosage form (for example, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients;

H. "New drug" shall have the meaning as set out in 21 U.S.C. § 321(p);

I. "Sterile drug" shall have the meaning as set out in 21 U.S.C. § 353b(d)(5);

J. "Days" shall refer to calendar days unless otherwise stated;

K. "FDA" shall mean the United States Food and Drug Administration; and

L. "Defendants' facility" shall refer to the facility located at 2401 South Foothill Drive, Suite D, Salt Lake City, Utah, 84109, and any other location(s) (including any new locations) at or from which, at any time in the future, any Defendant, directly or indirectly, manufactures, processes, packs, labels, holds, and/or distributes drugs, whether or not any Defendant has an ownership interest in the business.

10. On July 14, 2015, Defendants' facility located at 2401 South Foothill Drive, Suite D, Salt Lake City, Utah, 84109, was registered with FDA as an outsourcing facility pursuant to 21 U.S.C. § 353b. Isomeric re-registered as an outsourcing facility pursuant to 21 U.S.C. 353b most recently on January 25, 2017.

11. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing, processing, packing, labeling, holding, and/or distributing any drugs manufactured at and/or from Defendants' facility, unless and until:

A. Defendants ensure that the facilities, methods, and controls used to manufacture, process, pack, label, hold, and/or distribute drugs are established, operated, and

administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B);

B. Defendants ensure that each and every drug that Defendants intend to manufacture, process, pack, label, hold, and/or distribute at or from their facility satisfies all of the provisions of 21 U.S.C. § 353b, including but not limited to:

(1) Drug labeling at 21 U.S.C. § 353b(a)(10);

(2) Facility registration at 21 U.S.C. § 353b(b)(1);

(3) Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

(4) Drug reporting at 21 U.S.C. § 353b(b)(2); and

(5) Adverse event reporting at 21 U.S.C. § 353b(b)(5);

C. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert") who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendants, their officers or directors, or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are established, operated, and administered in conformity with CGMP, and to recommend and direct the implementation of corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten (10) days after retaining any such CGMP Expert;

D. Defendants submit a protocol that identifies the work plan for the CGMP Expert and the methodology that shall be used by the CGMP Expert (the "Work Plan") to: (1) conduct inspection(s) of Defendants' facility as described in paragraph 11.E; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacturing, processing, packing, labeling, holding, and/or distribution of drugs will be

continuously administered in conformity with CGMP. Defendants shall not implement the Work Plan prior to receiving FDA's written approval of the Work Plan, and in no circumstances shall FDA's silence be construed as a substitute for written approval;

E. The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants in August 2015, June 2016, and March 2017, and performs comprehensive inspection(s) of Defendants' facility and the methods and controls used to manufacture, process, pack, label, hold, and/or distribute drugs to determine whether Defendants' facility, methods, and controls are, at a minimum, in conformity with CGMP and are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B). The CGMP Expert shall, at a minimum, evaluate whether:

(1) Defendants have cleaned, sanitized, and satisfactorily maintained the entire facility, including the equipment and utensils, as necessary to effectively address the risks associated with aseptic processing, at appropriate intervals to ensure the safety, identity, strength, quality, and purity of Defendants' drugs;

(2) Defendants have established and implemented an adequate cleaning and disinfection program, which they have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture drugs;

(3) Defendants have established and implemented an adequate environmental monitoring program to: (a) ensure that all sterile and/or aseptic operations are properly monitored (including personnel, surfaces, and air quality); (b) include scientifically sound pre-established limits; and (c) ensure that Defendants identify, review, and address any results that exceed the pre-established limits and any adverse trends;

(4) Defendants have established and implemented adequate written procedures designed to prevent microbiological contamination of drug products purporting to be

sterile including, but not limited to, procedures for dynamic smoke studies, media fill simulations, and validation of all aseptic and sterilization processes;

(5) Defendants have established adequate control systems necessary to prevent contamination during aseptic processing including, but not limited to, an air supply filtered through high-efficiency particulate air (HEPA) filters under positive pressure;

(6) Defendants have established and implemented adequate written standard operating procedures ("SOPs") for manufacturing, holding, and distributing sterile drugs;

(7) Defendants conform to written procedures for production and process control designed to assure that Defendants' drug products have the identity, strength, quality, and purity they purport or are represented to possess, and that any deviation from the written procedures are recorded and justified;

(8) Defendants have established and implemented a written program designed to ensure that any automatic, mechanical, or electronic equipment used in the manufacture, processing, packing, or holding of a drug product is routinely calibrated, inspected, or checked to assure proper performance, and that written records of those calibration checks and inspections are maintained;

(9) Defendants have established and implemented an adequate testing program designed to assess the stability characteristics of Defendants' drug products;

(10) Defendants have established and implemented written SOPs to ensure that an adequate number of batches of each drug product is tested to determine an appropriate expiration date;

(11) Defendants have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate and documented laboratory determination of satisfactory conformance to pre-established final specifications for the drug product;

(12) Defendants have established and implemented written SOPs to ensure that Defendants: (a) thoroughly investigate and document in a timely manner, and retain such documents, any unexplained discrepancy or the failure of a batch of drug product, whether or not the batch has already been distributed, or any of its components, to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same product and other products that may have been associated with the specific failure or discrepancy; and (b) take required and timely corrective actions for all products that fail to meet specifications, and create and maintain documentation of such corrective actions;

(13) Defendants have established and implemented written SOPs to ensure that the Defendants thoroughly investigate and document in a timely manner any drug complaints, returns, or adverse events, and any associated trends in these product quality deviations and/or problems, and take any needed corrective actions in a timely manner;

(14) Defendants' employee training and qualification practices are adequate including, but not limited to, employee training and qualification in CGMP, inspection techniques, aseptic techniques, media fill processes, and procedures for responding to product quality deviations; and

(15) Defendants have established a quality control unit that has the responsibility and authority to approve or reject, among other things, drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated;

F. The CGMP Expert certifies in writing to FDA and Defendants that:

(1) The CGMP Expert has inspected Defendants' facility, methods, and controls used to manufacture, process, pack, label, hold, and/or distribute drugs;

(2) All deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected;

(3) Defendants have undertaken corrective actions to ensure that their facility, methods, and controls are adequate to prevent drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B); and

(4) Defendants' facility, methods, and controls comply with CGMP. As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the inspection(s) conducted under paragraph 11.E;

G. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all the deviations brought to Defendants' attention by FDA, the CGMP Expert, or any other source; and

(2) Ensure that Defendants' facility, methods, and controls used to manufacture, process, pack, label, hold, and/or distribute drugs will be continuously administered and operated in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B);

H. Defendants establish and maintain a system to report to FDA through the MedWatch reporting system all adverse drug experiences (in the manner described in 21 C.F.R. § 310.305 and/or 21 C.F.R. § 314.80) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after initial receipt of the adverse event information triggering a MedWatch report;

I. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 27, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after initial receipt of information triggering the Field Alert Report;

J. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants are in compliance with

the requirements of this Decree, the Act, and its implementing regulations, and whether Defendants' facility, methods, and controls are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B); and

K. Following FDA's inspection(s), FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 11.A–11.I of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

12. Within thirty (30) days after entry of this Decree, Defendants shall, under FDA's supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state laws.

13. After Defendants have complied with paragraph 11, and received written notification from FDA under paragraph 11.K, Defendant shall retain an independent person who meets the criteria described in paragraph 11.C and is qualified to assess Defendant's compliance with paragraph 11 (the "Auditor") to conduct audit inspections of Defendants' facility. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain such Auditor. After Defendants receive written notification from FDA under paragraph 11.K, audit inspections under this paragraph shall commence no less frequently than once every four (4) months for a period of one (1) year, and once every six (6) months thereafter for an additional four (4) year period.

A. At the conclusion of each audit inspection described in this paragraph, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The

Audit Report shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report. The Audit Report shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) days after the date each audit inspection is completed. In addition, Defendants shall maintain all Audit Reports in a separate file at Defendants' facility to which the report pertains and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report, correct those deviations, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, Defendants shall ensure that the Auditor reports in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

14. Upon receipt of written notification from FDA under paragraph 11.K, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B), or misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce;

C. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

15. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the CGMP Expert, and/or the Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act and/or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations, FDA may, as and when it deems necessary, notify

Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, processing, packing, labeling, holding, and/or distribution of any and all drug(s);

B. Recall specified drugs manufactured, processed, packed, labeled, held, and/or distributed by Defendants. The recalls(s) shall be initiated within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall, under FDA's supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

E. Issue a safety alert with respect to a drug manufactured, processed, packed, labeled, held, and/or distributed by Defendants; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act and/or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

16. The following process and procedures shall apply in the event that FDA issues an order under paragraph 15:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 25.

D. The process and procedures set forth in paragraphs 16 (A)–(C) shall not apply to any order issued pursuant to paragraph 15 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to

challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 25.

Any cessation of operations or other action described in paragraph 15 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. In no circumstance shall FDA's silence be construed as a substitute for written notification. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in this paragraph and paragraph 15, at the rates specified in paragraph 18. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

17. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to Defendants' facility including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples, without charge to FDA, of finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, processing, packing, labeling, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is

separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

18. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $93.26 per hour and fraction thereof per representative for inspection work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

19. Within three (3) days after becoming aware of any of the following information about any drugs manufactured, processed, packed, labeled, held and/or distributed at or from Defendants' facility, Defendants shall submit to FDA at the address specified in paragraph 27, a product quality report describing all information pertaining to any:

A. Product and/or manufacturing defects that could result in serious adverse drug experiences;

B. Mislabeling or mix-ups, including incident(s) that causes any drug or its labeling to be mistaken for, or applied to, another article; and/or

C. Contamination, including any bacteriological or fungal contamination, or any significant chemical, physical, or other change or deterioration, or lack of stability or incorrect potency, in any drug.

20. Within seven (7) days after entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at Defendants' facility, and publish the Decree on any internal and/or publically-available website maintained and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted at Defendants' facility and published as described herein for as long as the Decree remains in effect.

21. Within seven (7) days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within seven (7) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. In the event that Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days after each time Defendant becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

Within seven (7) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

23. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of any of Defendants' businesses, including incorporation, reorganization, relocation, bankruptcy, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure, responsibility of any individual defendant, or identity of Isomeric, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to any such assignment, change of responsibility of any individual defendant, or change in ownership.

24. If any Defendant fails to comply with any provision of this Decree, the Act and/or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: seventeen thousand dollars ($17,000) in liquidated damages for each day such violation continues; an additional sum of seventeen thousand dollars ($17,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drug products that have been manufactured, processed, packed, labeled, held, or distributed in violation of this Decree, the Act, and/or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and,

to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

26. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all attorneys' fees (including overhead) and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, court costs, and any other costs or fees incurred by the United States in bringing such an action.

27. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," and shall be addressed to the Director, Office of Pharmaceutical Quality Operations Division IV, Denver Federal Center, BLDG 20, P.O. Box 25087, Denver, CO 80228. An electronic copy shall be sent to orapharm4opdiv4mgmt@fda.hhs.gov.

28. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

29. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with all applicable laws and regulations and this Decree for a period of at least sixty (60) months after satisfying all of their obligations under this Decree, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

30. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 3rd day of August, 2017.

ROBERT J. SHELBY
United States District Judge

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

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WILLIAM O. RICHARDSON
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